Remarks

This Amendment is in response to the Office Action dated **October 17, 2007**. The Office Action: **1)** rejected claim 18 under 35 U.S.C. § 112 ¶ 2 for allegedly failing to point out and claim the invention, **2)** rejected claim 18 under 35 U.S.C. § 101 for allegedly setting forth a use without steps, **3)** rejected claims 1-11, and 14-17 under 35 U.S.C. § 102(e) over Published Application U.S. 2002/0193463 (hereinafter Jones), and **4)** rejected claims 12-13 under 35 U.S.C. § 103(a) over Jones in view of general conditions disclosed in the prior art. These items will each be addressed according to the above enumeration.

1) 35 U.S.C. § 112 ¶ 2 Rejection of Claim 18

The Office Action rejected claim 18 under 35 U.S.C. § 112 ¶ 2 for allegedly failing to point out and distinctly claim the invention. Specifically the Office Action stated that merely stating a use does not make clear how the invention is actually practiced. Accordingly, Applicant has amended claim 18 to properly recite a method comprising distinct steps.

2) 35 U.S.C. § 101 Rejection of Claim 18

The Office Action rejected claim 18 under 35 U.S.C. § 101 for allegedly setting forth a use without steps. As previously stated, instant claim 18 properly sets fourth steps in a method.

3) 35 U.S.C. § 102(e) 2 Rejection of Claims 1-11 and 14-17

The Office Action rejected claims 1-11, and 14-17 under 35 U.S.C. § 102(e) over Jones. The claimed embodiments however are unlike Jones because the properties and effects of

the composite material taught by Jones are unlike the properties and effects of the instant claims. Specifically, Jones does not disclose filler particles that: **a)** are non-porous, **b)** have smooth surfaces, nor **c)** do not shrink excessively. These differences are made clear both in Jones itself and more specifically in the attached Jones-EP-Response. The Jones-EP-Response is a document submitted by the Applicant of Jones in its co-pending sister European prosecution for European Application 99957492.4. Because European Application 99957492.4 claims priority from Jones and is directed to the same specification, it is a proper source for understanding exactly what Jones does and does not disclose.

3a) One significant difference between Jones and the claims is that Jones discloses a porous surface and the claims are directed to a non-porous surface. Jones utilizes a process including wet chemical synthesis followed by a heat treatment to produce material with high fracture toughness. (Jones, ¶ [0059]). This process to obtain a filler material with fracture toughness however also results in the material being porous. (Jones-EP-Response, Page 3 ¶ 1, and further described in Jones-EP-Response FIGs. 1 and 2 on Pages 6-8). In contrast, the smooth surface of the claimed filler material in non-porous. This smooth surface can be seen in Pages 29-31 of the document labeled in PAIR as Certified Copy of Foreign Priority Application dated 05/05/2005 (hereinafter Priority-Application). Priority-Application pages 29-31 contain SEM photographs of the claimed material which are clearly smooth. For the convenience of the Examiner, copies of these Priority-Application photographs taken from PAIR are enclosed with this amendment.

3b) Another significant difference between Jones and the claims is that Jones has a bumpy surface and the claims are directed to a smooth surface. This difference is apparent in contrasting the pictures of Jones-EP-Response FIGs. 1 and 2 on Pages 6-8 with the pictures of

Priority-Application pages 29-31.

3c) Finally the claims describe a material which has superior properties than Jones. Because of its bumpy surface, Jones' particles impede the compatibility of the particle's surface with matrix material. In contrast the smooth surface of the claimed embodiments, are not so impeded. As a result, the claimed material has a higher maximum fraction of filler than Jones so it has improved mechanical properties such as less shrinkage after polymerization than Jones does.

As a result of the above it is clear that the claims describe a composite material with properties not disclosed by Jones. For at least these reasons, this rejection is traversed.

4) 35 U.S.C. § 103(a) over Jones and general conditions

The Office Action rejected claims 12-13 under 35 U.S.C. § 103(a) over Jones in view of general conditions disclosed in the prior art. As previously mentioned in section 3 of these remarks, Jones does not disclose filler particles that are non-porous, have smooth surfaces, or that do not shrink excessively. Because the Office Action provided no other evidence to support the contention that filler particles with these properties are general conditions disclosed in prior art this rejection is also traversed.

Conclusion

Based on the previous remarks, Applicants respectfully submits this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-18 are requested.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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Enclosures: Copy of Jones-EP-Response
Pages 29-31 of Priority Application

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EPO - Munich
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24. Juli 2006

July 24, 2006

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Re: European Patent Application
No.: 99 957 492.4 - 2108
New Age Biomaterials,Inc.
Our Ref.: EA-PCT-11459

Response to the Communication dated January 19, 2006

A new set of claims is filed. For disclosure purposes, reference is made to the original claims and the description on page 10 lines, 2nd paragraph to page 11, line 11.

Moreover, a comparative test report and SEM photographs are filed in support of inventive activity of the present invention.

I. Novelty

D1 does not disclose a filled dental material containing ceramic particles having a preselected shape obtainable by a wet chemical synthesis. According to a wet chemical method, particles are prepared by increasing the particle size of a precursor by a series of chemical condensation and related polymerisation reactions.

D1 discloses particles which are obtained by size reduction of a precursor by shaping based on chemical degradation or physical measures. According to Examples I to IV of D1, particles are prepared by an etching technique from a layer of the filler material. Example V suggests as an alternative method the use of a laser

for ablating particles from a sheet. According to Example VI, carbon fibers are produced by pyrolysis of precursor fibers. Example VII suggests to align primary particles by using magnetic attraction or ultrasound. Moreover, the general disclosure does not disclose any wet chemical method for the preparation of particles.

Given that D1 does not disclose ceramic particles obtainable by a wet chemical method of the present invention, the particles of D1 differ with regard to the combination of properties of size, shape, topography and chemistry.

The definition that the particles of the invention are obtainable by a wet chemical method is believed to address also the objection under item 3 of the Communication in that a hollow vessel obtainable by a wet chemical process shows apertures into which the matrix may penetrate and interlock. An example for a hollow sphere obtainable by a wet chemical method is shown by the enclosed SEM photograph of Fig 2. The hollow spheres obtainable by a wet chemical methods are in fact hollow vessels into which the matrix may interlock through an aperture on the top and bottom of the particles and the porous vessel walls. SEM photograph of Fig. 3 further illustrates the porous nature of the surface of the walls of the hollow spheres.

II. Inventive Step

Using D1 as the closest prior art, the difference between the subject matter of new claim 1 and the disclosure of D1 is based on the fact that D1 does not disclose a filled dental material having improved mechanical properties comprising 5 to 35 percent by weight of ceramic particles having a preselected shape obtainable by a wet chemical synthesis, which is selected from the group consisting of (i) doughnuts, (ii) multi-dimples, (iii) hollow spheres, (iv) nuggets, and (v) mixtures of shapes according to (i) to (iv) and optionally spheres, rods and fibers, wherein the filled dental material is improved due a mechanical interlocking of the ceramic particles within the matrix.

The differences between the subject matter of new claim 1 and the disclosure of D1 give rise to a dramatic effect with regard to fracture toughness: As shown by the enclosed test report and table 3 on page 21 of the application as filed, a dental material containing 20 % by weight of the ceramic particles according the present invention can produce fracture toughness values significantly higher than any commercial dental composite material. The fracture toughness is close to the fracture toughness of typical tooth dentine (above 3 MPa $m^{0.5}$) whereas commercial dental composite material are more than 30 % weaker (less than 2 MPa $m^{0.5}$).

Departing from the closest prior art, it is the objective problem of the present invention to provide a filled dental material having improved mechanical properties comprising a resin matrix and a filler component, whereby the dental material has a significantly improved fracture toughness, high ratio opacity and improved resistance to wear.

This problem was solved according to new claim 1. As shown with the enclosed comparative test and the example described on page 20, line 3 to page 21, first paragraph, the incorporation of only 20 % of the particles obtainable by a wet chemical method according to the invention into 10 different conventional composite material provides an increase of fracture toughness of at least 50%. Moreover, the fracture toughness is in the order of the fracture toughness of natural dentin.

The present invention provides for the first time a filled dental material containing a filler additive which may be used in small amounts (5 to 35 % by weight based on the total filler loading of ceramic particles) for significantly increasing fracture toughness and resistance to wear by mechanical interlocking of the particles close to the surface of the cured dental material. Surprisingly, a small amount of particles having a specific preselected shape according to the invention is sufficient to dramatically stabilize the cured dental material by mechanical interlocking even in the presence of significant amounts of further conventional filler particles. This window of opportunity for increasing fracture toughness, ratio opacity and resistance

to wear, which is defined according to the invention by amount and shape of a filler additive is without precedent in the prior art.

None of the cited references is able to render obvious the problem solution relationship of the present invention for the following reasons.

1. There is nothing in the prior art which would suggest that a dramatic increase of the fracture toughness of a filled dental material up to the level of natural dentin is possible at all. Therefore, the skilled person would not have any reason to expect that a material containing a resin matrix may be provided which has a fracture toughness of such an natural inorganic hard tissue.

2. D1 does not teach particles obtainable by a wet chemical method. Therefore, D1 cannot render obvious the specific shapes obtainable according to the present invention.

3. The specific filler material of D1 are unable to solve the problem of the present invention since the filler material suggested by D1 is prepared shaping methods using chemical or physical degradation. It is not clear how a material which may easily shaped by etching of laser ablation, is able to be used as a filler in the aggressive environment of the mouth wherein chemical and mechanical degradation give rise to the problem which is addressed by the present invention.

4. D2 and D3 do not relate to the specific shapes used in the present invention. Therefore, the skilled person cannot find any hint or suggestion in D2 or D3 for arriving at the present invention departing from the closest prior art D1.

It is respectfully believed that the claims now on file are allowable. If this should not be the case, an informal interview is requested, or if necessary, formal oral proceedings. Any amendment to the description is postponed until the allowable

wording of the claims is known.

Respectfully submitted,

Nikolai F. Hartz
Patent Attorney

Enclosure
New claims 1 to 8
Test Report
SEM Photographs

EXPERIMENTAL TESTS

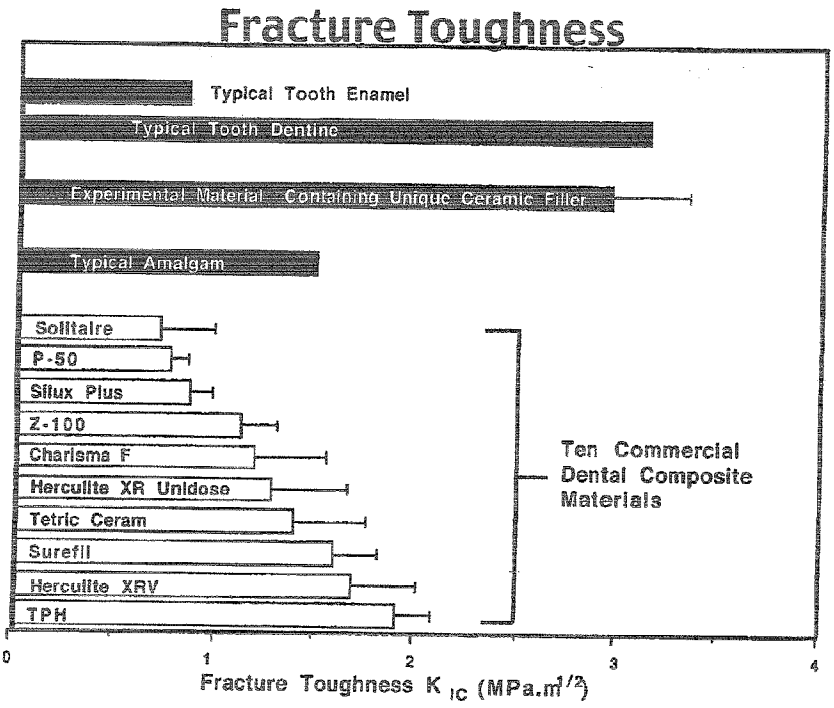


Figure 1.

The above data illustrates typical fracture toughness values for dental amalgam, natural tooth enamel and tooth dentine, as well as the mean (± sd) for ten commercial dental composite materials. The data for the experimental material indicates that the incorporation of 20% by weight of the unique shaped ceramic particles can produce fracure toughness values significantly higher than any commercial dental composite material. Values equivalent to that of natural dentine indicate that this development represents a major breakthrough in materials science.

FIGURE 2

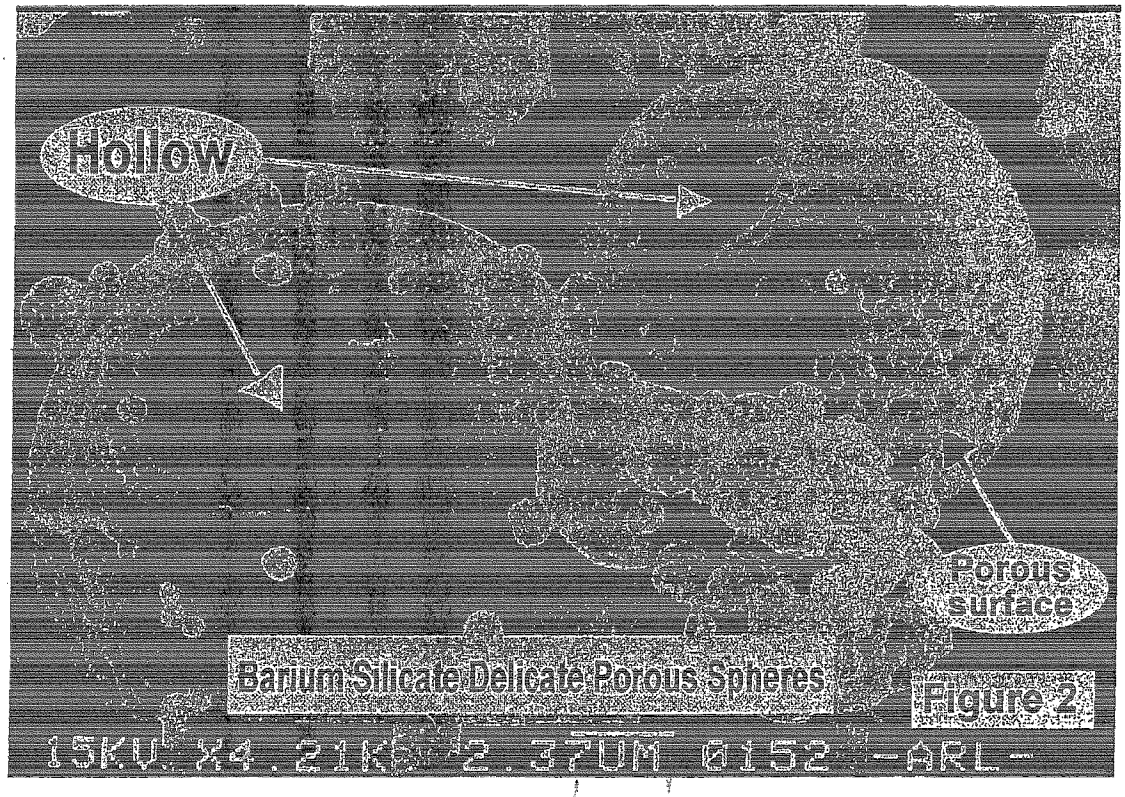
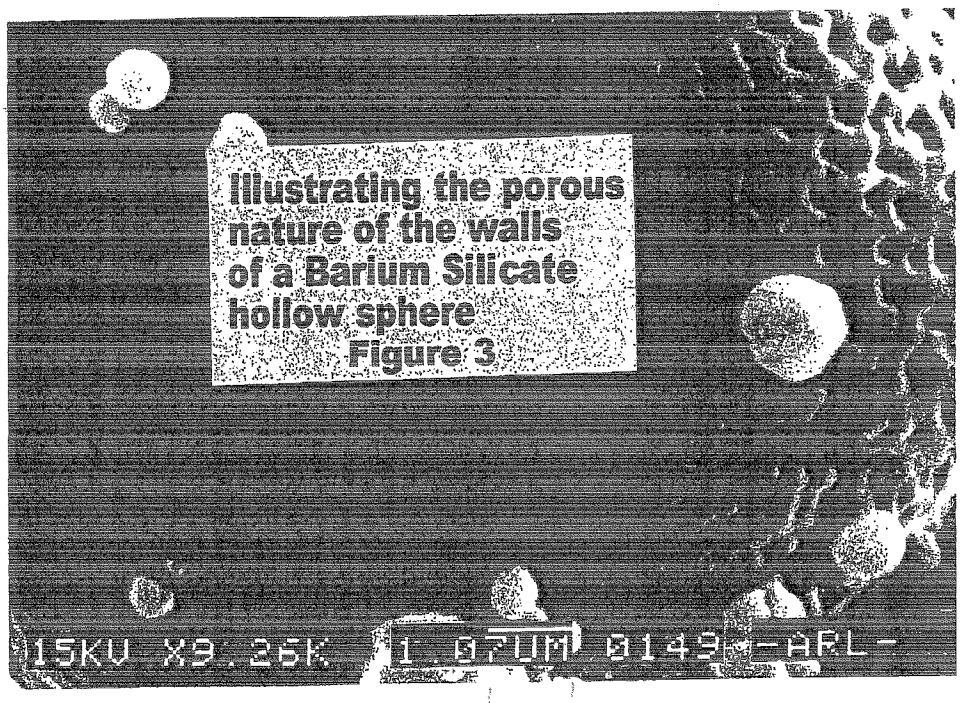

Hollow
Porous Surface
Barium Silicate Delicate Porous Spheres
Figure 2
15KV X4.21K 2.37UM 0152 -ARL-

FIGURE 3


Illustrating the porous
nature of the walls
of a Barium Silicate
hollow sphere
Figure 3
15KU X9.26K 1.07UM 0149 -ARL-

New Claims

1. A filled dental material having improved mechanical properties comprising:

   (a) a resin matrix and

   (b) a filler component;

   wherein said filler component comprises based on the total filler loading of ceramic particles, 5 to 35 percent by weight of ceramic particles having a preselected shape obtainable by a wet chemical synthesis;

   said preselected shape selected from the group consisting of

   (i) doughnuts,

   (ii) multi-dimples,

   (iii) hollow spheres,

   (iv) nuggets, and

   (v) mixtures of shapes according to (i) to (iv) and optionally spheres, rods and fibers,

   wherein the filled dental material is improved due to mechanical interlocking of the ceramic particles within the matrix.

2. A filled dental material as in claim 1, wherein said multi-dimpled shaped particles are porous.

3. A filled dental material as in claim 1, wherein said multi-dimpled shaped particles are solid.

4. A filled dental material as in claim 1, wherein said filler particles are produced by wet chemical synthesis of a material selected from the group consisting of zirconium, silica, barium, titanium, strontium, alumina, mullite or mixtures thereof.

5. A filled dental material as in claim 1, wherein said filler particles are a mixture

of silica and from about 3 to about 40 percent by weight of ZrO_2.

6. A filler as in claim 4, wherein said filler particles are a mixture of silica and from about 10 to about 80 percent by weight of BaO.

7. A filler as in claim 4, wherein said filler is a mixture of silica and from about 3 to about 40 percent by weight of TiO_2.

8. A filler as in claim 7, wherein said filler is a mixture of silica and from about 10 to about 80 percent by weight of SrO.

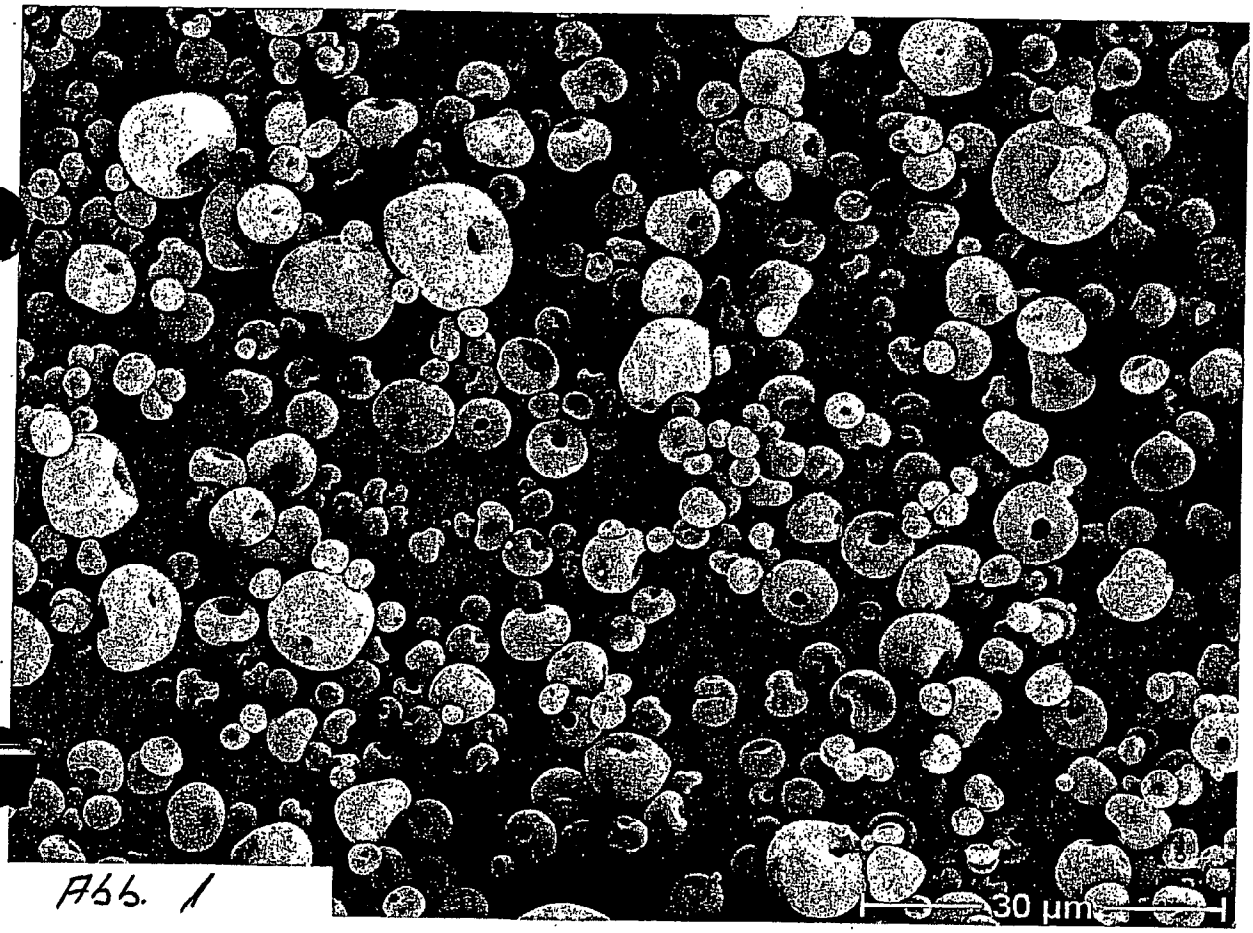


Abb. 1

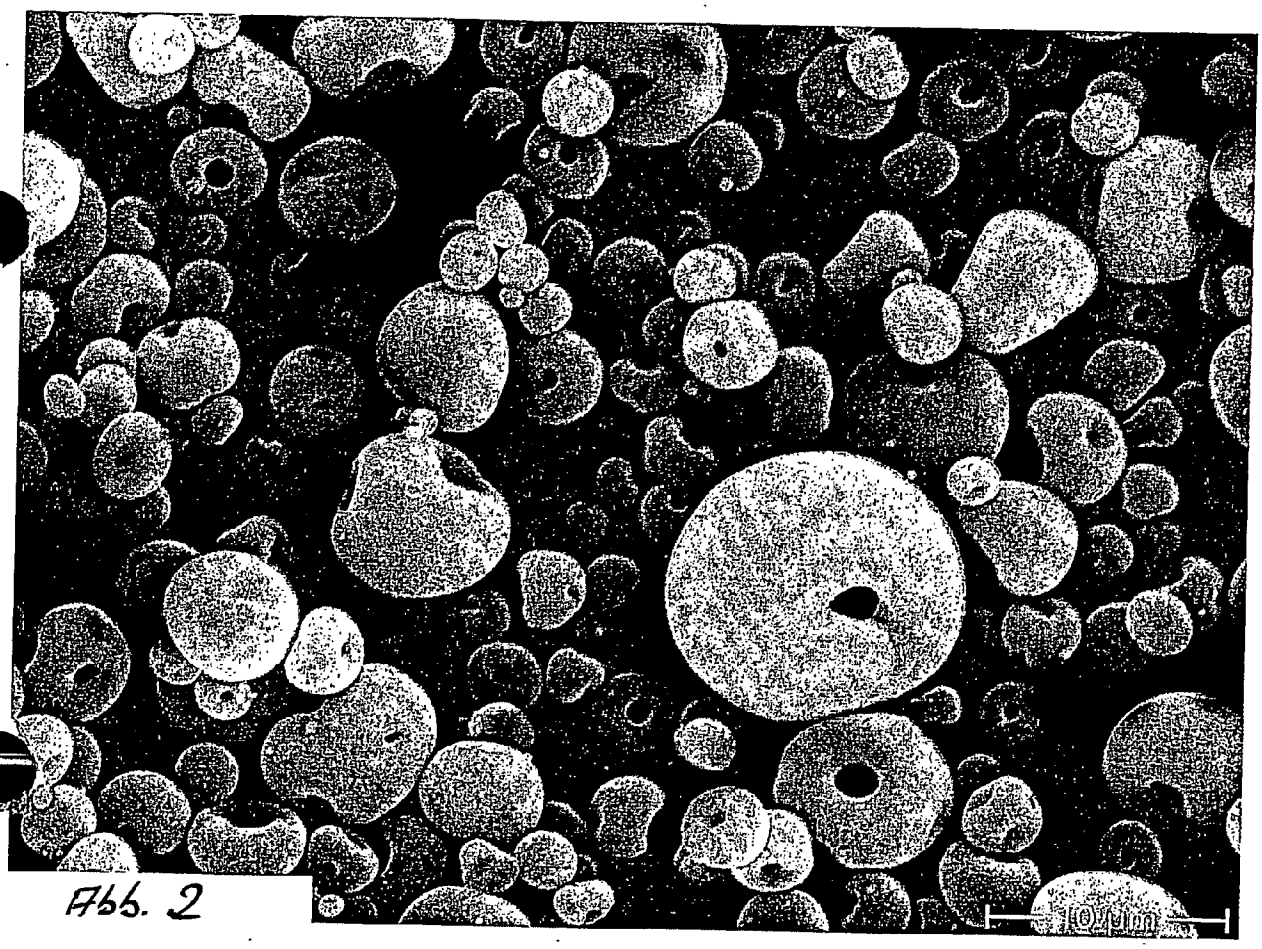


Fig. 2

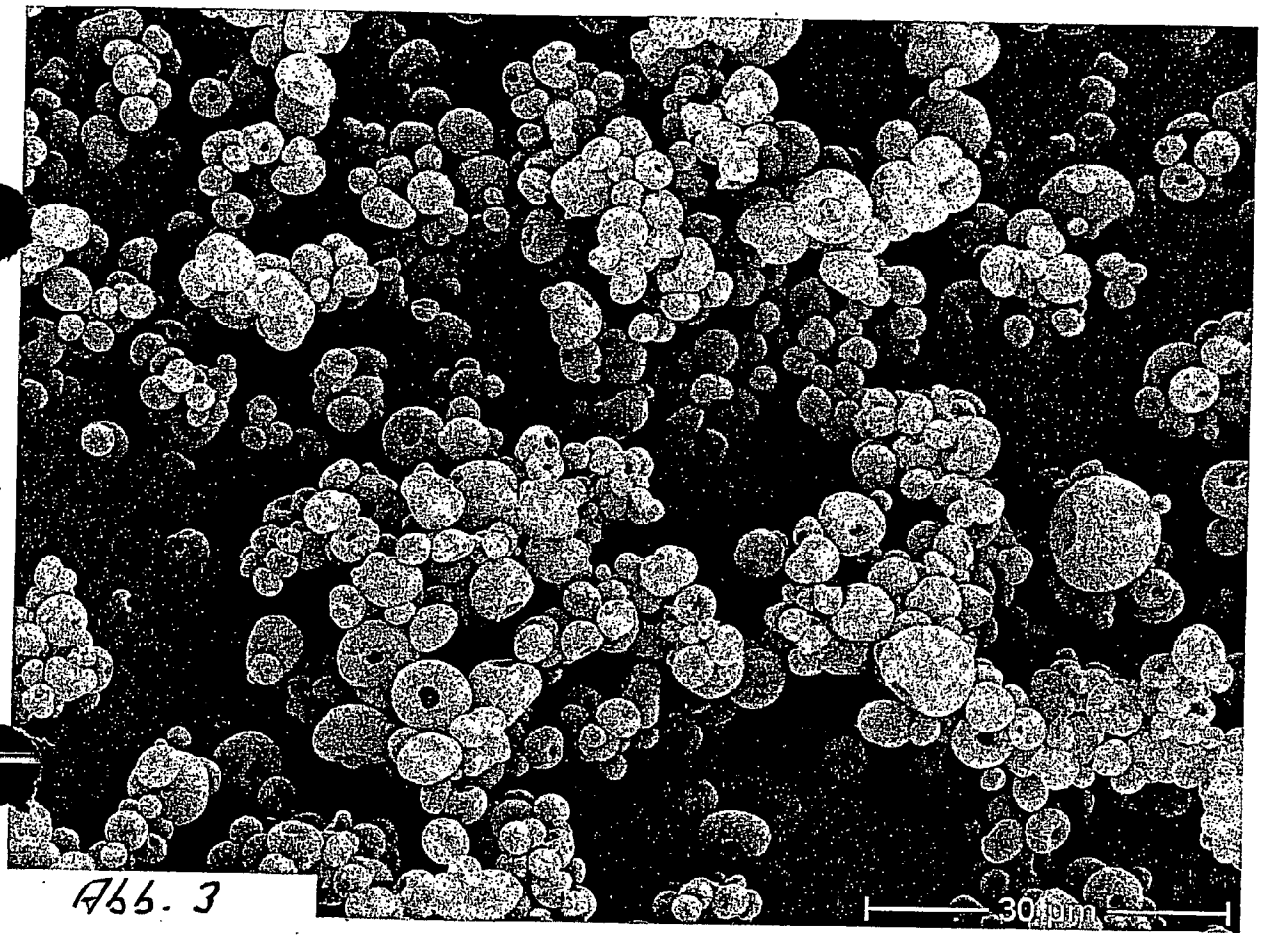


Abb. 3